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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HOFFMANN-LA ROCHE INC.,	:
	:
Plaintiff,	: Honorable Stanley R. Chesler, U.S.D.J.
	:
v.	: Civil Action No. 2:10-cv-4540 (SRC)(MAS)
	:
ORCHID CHEMICALS &	:
PHARMACEUTICALS LTD.,	:
ORCHID HEALTHCARE, ORCHID	: Return Date: February 22, 2011
PHARMACEUTICALS INC., AND	:
ORGENUS PHARMA INC.,	: <u>ORAL ARGUMENT REQUESTED</u>
	:
Defendants.	:

**PLAINTIFF'S BRIEF IN OPPOSITION TO THE ORCHID DEFENDANTS'
MOTION FOR JUDGMENT ON THE PLEADINGS WITH RESPECT TO
U.S. PATENT 4,927,814**

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INTRODUCTION

Plaintiff Hoffmann-La Roche Inc. (“Roche”) respectfully submits this Memorandum of Law in opposition to Orchid’s Rule 12(c) motion seeking judgment on Orchid’s affirmative defense and counterclaim that Roche’s U.S. Patent 4,927,814 (“the ‘814 patent”) is expired due to an alleged terminal disclaimer (hereinafter, the “terminal disclaimer defense.”).

The instant case concerns an ibandronate sodium generic drug product covered by Roche’s ‘814 patent which will expire a little over one year from now -- on March 17, 2012. The issues in this new Orchid case overlap in large part with more advanced litigations currently pending before this Court between Roche and defendants Apotex and Cobalt, who are other generic drug manufacturers (collectively, the “Apotex and Cobalt ‘814 Patent Actions”). Orchid seeks to have its case consolidated with these earlier actions, but seeks to add a terminal disclaimer defense, which the Court precluded Apotex from raising last year.

Roche has moved to preclude the defense in this Orchid action or, alternatively, to stay this Orchid action until judgment is entered in the Apotex and Cobalt ‘814 Patent Actions. (*See* Dkt. Nos. 26 and 27, C.A. No. 10-4540.) Roche requests that its motion to preclude or stay be considered before the Court addresses the present Rule 12(c) motion.

SUMMARY OF ARGUMENT

Orchid's Rule 12(c) motion on its terminal disclaimer defense should be denied because there are disputed issues of fact inasmuch as Roche denies that the '814 patent is subject to a terminal disclaimer and Orchid disputes Roche's interpretation of what is in the United States Patent and Trademark Office (the "PTO") record¹. It is black letter law that "[i]f a material issue of fact remains in dispute, the court must deny the Rule 12(c) motion." *See* Baicker-McKee *et al.*, *Federal Civil Rules Handbook* (2011), Rule 12(c) Commentary at 465 (emphasis added). The Court has previously held that it "is not satisfied" that the terminal disclaimer defense "is necessarily a purely legal issue" and found that there are material issues of fact in dispute. (*See* Transcript of April 15, 2010 Court Hearing, Borchetta Decl., Exh. A at 41.) In addition, if the Court elects to address Orchid's Rule 12(c) motion on the merits, Orchid's motion should nonetheless be denied for the additional reason that a failure to pay maintenance fees on one patent does not

¹ While Apotex's counsel had previously argued that "there's a lot here [in the prosecution history] that doesn't necessarily mean what on its face it might appear to mean," Orchid takes the exact opposite position and simply ignores contrary facts in the PTO record or brands them "irrelevant." (*See* Apotex argument at p. 14 of Transcript of April 15, 2010 Court Hearing, attached as Exh. A to Declaration of Frank J. Borchetta (hereinafter, "Borchetta Decl."), dated January 28, 2011, which was submitted in support of Roche's motion to stay this case or to preclude Orchid's terminal disclaimer defense and counterclaim, at Dkt. 27, C.A. No. 10-4540.)

bring a terminal disclaimer into effect for another patent where a disclaimer was filed to overcome a provisional obviousness-type double patenting rejection.

FACTS

As Roche's counsel explained previously, the PTO had granted a patent term extension ("PTE") extending the term of the '814 patent under 35 U.S.C. § 156. (*See* Transcript of April 15, 2010 Court Hearing, Borchetta Decl., Exh. A at 6; *see also* Certification Extending Patent Term, Orchid Answer Exh. C-3 at R2000421.) Moreover, Roche disclosed the facts underlying this purported defense to the PTO in connection with its PTE application, and this was read into the record at oral argument. (*See* Transcript of April 15, 2010 Court Hearing, Borchetta Decl., Exh. A at 7: "The U.S. Patent and Trademark Office had this information. They were charged with determining whether or not the '814 patent was entitled to extension under the remedial statute 35 U.S.C. 156, and the Patent and Trademark Office did in fact determine that Roche was so entitled.") Orchid now challenges the correctness of the grant of this patent term extension and, in effect, argues that the PTO made a mistake because the '814 patent had allegedly been terminally disclaimed over another patent that had already expired due to failure to pay maintenance fees. Roche disputes that the '814 patent was terminally disclaimed at the time of its patent term extension grant.

The underlying facts are these. On July 9, 1987, Boehringer Mannheim GmbH (which was acquired by Roche in 1998), filed two applications: (1) Application No. 71,471 (“the ‘471 application”), which issued as the ‘814 patent on May 22, 1990; and (2) co-pending Application No. 71,320 (“the ‘320 application”), which issued as the ‘157 patent two months later on July 17, 1990. (*See* the ‘814 and ‘157 patents, Orchid Answer Exhs. A and B, respectively.)²

It is Roche’s position that there was no terminal disclaimer in effect for the ‘814 patent when it issued. (*Id.*) It is also Roche’s position that while terminal disclaimers were submitted to overcome provisional rejections in both co-pending applications for the ‘814 and ‘157 patents, only the terminal disclaimer in the ‘157 patent was made effective because the ‘157 patent was the later-issued patent. (*Id.*)

The PTO issued “provisional” obviousness-type double patenting³ rejections in both the ‘471 and ‘320 applications and the applicants submitted

² “Orchid Answer Exh.” refers to those exhibits attached to the Orchid Defendants’/Counterclaimants’ Answer and Counterclaim, dated September 30, 2010. (Dkt. No. 6, C.A. No. 10-4540.)

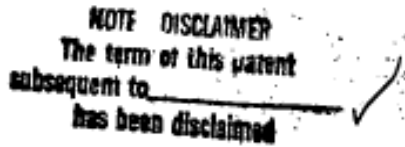
³ Obviousness-type double patenting is a judicially created doctrine that prohibits the issuance of claims in a later-issued patent that are not patentably distinct from the claims of a first patent, unless the patentee disclaims the term of the later patent beyond the expiration of the earlier one. *See Boehringer Ingelheim Int’l GmbH v. Barr Labs., Inc.*, 592 F.3d 1340, 1345 (Fed. Cir. 2010); *Eli Lilly & Co. v. Barr Labs. Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

terminal disclaimers in July 1989 in both pending ‘471 and ‘320 applications.⁴ (See April 4, 1989 Office Action and terminal disclaimer submitted on July 7, 1989 in the ‘814 file history, Orchid Answer Exh. C-2 at R2000155-158 and R2000198-200; *see also* April 4, 1989 Office Action and terminal disclaimer submitted on July 7, 1989 in the ‘157 file history, Orchid Answer Exh. D-2 at R2007647-7649 and R2007658-7660.)

Both file histories indicated that no terminal disclaimer dates were entered by PTO staff before either application issued as a patent: “The terminal data has been omitted from the label on the face of the file jacket since the related application is pending in your group or abandoned.” (See November 21, 1989 Communication in the ‘814 file history, Orchid Answer Exh. C-2 at R2000224, and the Dec. 7, 1989 Communication in the ‘157 file history, Orchid Answer Exh. D-2 at R2007686; emphasis in originals).

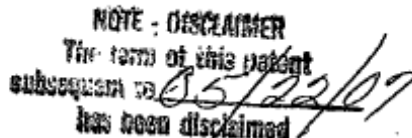
The label that was affixed to the ‘814 file history by PTO staff was left blank and still reads today, “NOTE DISCLAIMER The term of this patent subsequent to _____ has been disclaimed”:

⁴ In some instances, Orchid incorrectly refers to the Examiner’s April 4, 1989 rejection as a rejection for “obviousness-type double patenting” (*see, e.g.*, Orchid Br. at 10-11); however, this rejection was only a “provisional” rejection because the referenced claims were in a co-pending application that had not yet issued as a patent.



NOTE - DISCLAIMER
The term of this patent
subsequent to _____
has been disclaimed ✓

(See Orchid Answer Exh. C-1 at R2000011).⁵ In contrast, the ‘157 patent, as issued by the PTO, contains a notice that its term has been disclaimed. This is reflected in the label affixed to the ‘157 file history, which has been filled in and reads -- “NOTE - DISCLAIMER The term of this patent subsequent to 05/22/07 has been disclaimed”:



NOTE - DISCLAIMER
The term of this patent
subsequent to 05/22/07
has been disclaimed

(See Orchid Answer Exh. B and Exh. D-1 at R2007498.) The date entered here is 17 years from the date that the ‘814 patent was issued. This evidences that the ‘157 patent was terminally disclaimed over the earlier issued ‘814 patent -- not the opposite.

⁵ The MPEP stated at the time of the ‘814 patent prosecution -- as it does today -- that the PTO’s processing of terminal disclaimers includes, *inter alia*, “Providing the disclaimer data for printing.” (See MPEP § 1490, 5th Ed., Rev. 11 at 1400-22 (April 1989), attached as Exh. A to the Declaration of Paul B. Sudentas, dated February 7, 2011, accompanying this brief.) This further supports Roche’s position that no terminal disclaimer was made effective in the ‘814 patent because this “disclaimer data” was in fact left blank on the file wrapper for the ‘814 patent. (See ‘814 Patent File Wrapper, Orchid Answer Exh. C-1 at R2000011.)

The ‘814 patent issued on May 22, 1990 (Orchid Answer Exh. A), and the ‘157 patent issued two months later on July 17, 1990 (Orchid Answer Exh. B). Roche’s position is that the provisional obviousness-type double patenting rejection against the ‘814 patent became moot when this patent was issued first and was never made effective by the PTO because there was no “patent” for it to be disclaimed over.

Again, Roche’s position was explained in the ‘814 file history in an April 24, 2007 communication in connection with Roche’s request for patent term extension:

While a terminal disclaimer was submitted to the United States Patent and Trademark Office in the application that issued as the ‘814 patent, this terminal disclaimer was never made effective in the patent.

(See Orchid Answer Exh. C-3 at R2000413; emphasis added.) Thereafter, the PTO determined that the ‘814 patent was entitled to an extension under 35 U.S.C. § 156, extending the patent term of the ‘814 patent from July 9, 2007 up to and including March 17, 2012. (See Notice of Final Determination dated June 12, 2007, Orchid Answer Exh. C-3 at R2000417-418.)

ARGUMENT

I. The Legal Standard

Orchid’s own citation to *Sheridan v. NGK Metals Corp.*, 609 F.3d 239 (3d Cir. 2010) (Orchid Br. at 10) highlights the fact that “Judgment on the pleadings

‘will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law.’” *Id.* at 260 n. 25 (citation omitted); *see also Syndicate 1245 at Lloyd’s v. Walnut Advisory Corp.*, 721 F. Supp. 2d 307, 315 (D.N.J. 2010) (Wolfson, J.) (Rule 12(c) motion denied).

In addition, on Orchid’s Rule 12(c) motion, the Court must draw all inferences in the light most favorable to Roche. As this Court has reiterated, “[t]he standard for a motion for judgment on the pleadings under Fed. R. Civ. P. 12(c) is the same as that for a motion to dismiss under Fed. R. Civ. P. 12(b)....On a motion to dismiss for failure to state a claim, pursuant to Fed. R. Civ. P. 12(b)(6), the court must accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in the light most favorable to the non-moving party.” *Engers v. AT&T*, 2007 U.S. Dist. LEXIS 47, at *5-6 (D.N.J. Jan. 3, 2007) (Chesler, J.) (citation omitted; Rule 12(c) motion denied); *see also Horizon Healthcare Services, Inc. v. Allied National Inc.*, 2007 U.S. Dist. LEXIS 26352, at *10 (D.N.J. April 10, 2007) (Greenaway, Jr., J.) (Rule 12(c) motion denied). In deciding a Rule 12(c) motion, the Court “may consider matters of public record, orders and exhibits attached” to the pleading. *See Horizon Healthcare*, 2007 U.S. Dist. LEXIS 26352, at *10-11.

II. Orchid's Rule 12(c) Motion Should Be Denied Because There Are Material Issues of Fact in Dispute

Orchid's representation that a resolution of its Rule 12(c) motion is a legal question discernable from the prosecution history file is without merit because, as the Court has previously recognized when Apotex raised the identical defense, there are material issues of fact in dispute. Orchid's brief ignores the existence of factual disputes as to which discovery would be required.

Roche respectfully refers the Court to the prosecution histories of the '814 and '157 patents and the patents themselves. For example, Orchid ignores that the face of the '157 patent expressly notes at the "[*] Notice" section that the term of the '157 patent is disclaimed:

United States Patent [19] Gall et al.	[11] Patent Number: 4,942,157 [45] Date of Patent: * Jul. 17, 1990
[54] 1-HYDROXY-3-(N-METHYL-N-PROPYLAMINO)PROPANE-1,1-DIPHOSPHONIC ACID, PHARMACEUTICAL COMPOSITIONS AND METHODS OF USE .	FOREIGN PATENT DOCUMENTS 2534391 2/1977 Fed. Rep. of Germany . 2702631 7/1978 Fed. Rep. of Germany . 3623397 1/1988 Fed. Rep. of Germany . 1002300 3/1983 U.S.S.R. . 1254465 11/1971 United Kingdom .
[75] Inventors: Rudi Gall; Elmar Bosies, both of Mannheim, Fed. Rep. of Germany	OTHER PUBLICATIONS Von K.-H. Worms, et al., Z. Anorg. Allg. Chem., 457, 214-218 (1979). <i>Primary Examiner</i> —Anton H. Sutto <i>Attorney, Agent, or Firm</i> —Felfe & Lynch
[73] Assignee: Boehringer Mannheim GmbH, Mannheim, Fed. Rep. of Germany	[57] ABSTRACT
[*] Notice: The portion of the term of this patent subsequent to May 22, 2007 has been disclaimed.	The present invention provides 1-Hydroxy-3-(N-methyl-N-propylamino)propane-1,1-diphosphonic acid of formula
[21] Appl. No.: 71,320	
[22] Filed: Jul. 9, 1987	

(See '157 patent, Orchid Answer Exh. B.) The asterisk next to the Date of Patent refers to a Notice in the left-hand column indicating that "[t]he portion of the term

of this patent subsequent to May 22, 2007 has been disclaimed.” (*Id.*) There is no dispute that the ‘157 patent was terminally disclaimed over the ‘814 patent which issued two months earlier on May 22, 1990. In contrast, the ‘814 patent, as issued by the PTO, does not contain any asterisk next to the Date of Patent, nor any notice that the term has been disclaimed. (*See* ‘814 patent, Orchid Answer Exh. A.)

In addition, the disclaimer label on the file wrapper for the ‘471 application (which issued as the ‘814 patent) appears to have been crossed out by the PTO -- a material fact that Orchid dismisses.



(Orchid Answer Exh. C-1 at R2000011.) This is, of course, consistent with Roche’s belief that a terminal disclaimer, though filed provisionally, was never made effective for the ‘814 patent (because it issued before the ‘157 patent).

As this Court observed, discovery would be justified and necessary to resolve whether and why the PTO crossed out the terminal disclaimer label: “The Court is not satisfied that it is necessarily a purely legal issue. There indeed may very well be issues relating to what the entries meant, what the “X” meant, the “X” being, I gather, the cross-out entry on one copy of -- on the file wrapper.”

(Transcript of April 15, 2010 Court Hearing, Borchetta Decl., Exh. A at 41; emphasis added).⁶ Roche disputes Orchid's assertion that no fact discovery would be necessary or warranted, especially in light of this Court's previous findings. (See Transcript of April 15, 2010 Court Hearing, Borchetta Decl., Exh. A at 38-39: "[T]he Court is satisfied that, in fact, there is a reasonable demonstration which has been made in this case that additional discovery, particularly relating to the effect of various notations on the file wrappers, would be relevant.")

As such, discovery would be required as to at least "the effect of various notations on the file wrappers". (See Transcript of April 15, 2010 Court Hearing, Borchetta Decl., Exh. A at 38-39.) To date, there has been no fact, contention, or expert discovery on Orchid's new defense that the term of the '814 patent was somehow disclaimed over the term of the later-issued '157 patent.⁷ Fact discovery would be complicated and potentially protracted due to PTO requirements. (See Manual of Patent Examining Procedure ("MPEP") § 1701.01, and 37 C.F.R. § 104.22). As Roche detailed in its motion to stay or preclude, a substantial delay

⁶ Notwithstanding the Court's agreement with Roche that there may be issues relating to what the cross-out entry means, Orchid argues that "Roche's contention is not only speculative, but also immaterial." (See Orchid Br. at 13.)

⁷ Orchid criticizes Roche for not marching ahead with third party discovery of the PTO as soon as Orchid pleaded this as a defense (Orchid Br. at 10, n.3); however, a Rule 16 conference has not even been held in this action, and apparently Orchid is unaware that no discovery is permitted under the Federal Rules until after the parties have conducted their Rule 26(f) conference and submitted a proposed discovery plan to the Court. See Fed. R. Civ. P. 26(d).

at this late stage in the proceedings would result in significant delay in the trial of Roche's '814 patent and would be highly prejudicial to Roche.

Because of the existence of the material issues of fact in dispute outlined above, Orchid's Rule 12(c) motion for judgment on the pleadings should be denied.

III. Orchid's Terminal Disclaimer Defense Is Without Merit and Was Properly Rejected When Apotex Raised It and Should Be Rejected Now

The pivotal issue here is that Orchid's Rule 12(c) motion should be denied because there unquestionably are disputed issues of fact to be resolved. Thus, the merits of Orchid's terminal disclaimer claim need not be addressed.

However, if the Court were to entertain the merits of Orchid's claim, Roche states that Orchid's terminal disclaimer claim has no merits in view of both the Federal Circuit's decision in *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1374 (Fed. Cir. 2005) and the Court of Federal Claims' decision in *Boeing Co. v. United States*, 69 Fed. Cl. 397 (Fed. Cl. 2005). Even assuming that a terminal disclaimer was entered and became effective as to the '814 patent -- which Roche disputes -- a patentee's failure to pay maintenance fees on one patent does not extinguish the term of both⁸. See *Pharmacia*, 417 F.3d at 1374 ("Beyond their

⁸ Orchid implies that the MPEP provided guidance in drafting a terminal disclaimer which gives consideration to the effect of failure to pay maintenance fees. (See Orchid Br. at 7, ¶ 17.) However, the Forms available at MPEP § 1490 did not provide language with respect to failure to pay maintenance fees and are in fact

shared expiration date, however, two disclaimed patents maintain significant attributes of individuality...If [a patentee] does not pay the maintenance fee on one of the patents, that oversight would have no effect on the validity or enforceability of the other patent.”) (citations omitted; emphasis added).

Boeing is also on all fours here. In *Boeing*, to overcome double patenting, Boeing submitted a terminal disclaimer, which was issued in connection with Boeing’s ‘682 patent, to ensure that the ‘682 patent would not extend past the statutory termination date of certain earlier Boeing patents. Defendant claimed that because Boeing stopped paying its maintenance fees on the earlier patents in April 1996, that the ‘682 patent had also expired at the same time, in April 1996, because they were linked in the terminal disclaimer. *Boeing*, 69 Fed. Cl. at 423.

In rejecting Defendant’s argument, the *Boeing* Court “stressed the individuality of patents in limiting the impact of disclaimers,” *id.* at 423-424, and held that “the early expiration of Boeing’s earlier patents due to its choice not to pay the maintenance fees does not affect the expiration date of the full statutory term to which these earlier patents originally were entitled, and to which, and only which, the ‘682 patent was tied.” *Id.* at 425-426. The *Boeing* Court reasoned that “[t]o avoid such double-patenting, Boeing needed to disclaim only the portion of the ‘682 patent’s term that would have exceeded the statutory term of its prior

close in form to those at issue in *Boeing*. (See discussion in *Boeing* at 423, and MPEP § 1490, 5th Ed., Rev. 12 at 1400-22, Sudentas Decl., Exh. A.)

patents – it did not need to make the term of the ‘682 patent strictly dependent upon whether maintenance fees were paid on the latter patents.” *Id.* at 424.⁹

Here, the facts are even more compelling because there was no terminal disclaimer ever made effective in the ‘814 patent and therefore no portion of the ‘814 patent’s term was ever disclaimed or otherwise tied to the term of the ‘157 patent. Even if a terminal disclaimer had been issued in the ‘814 patent, the cases above conclusively show that the nonpayment of maintenance fees in the ‘157 patent would have no effect on the enforceability of the ‘814 patent.¹⁰

Orchid’s attempt to distinguish *Boeing* is also futile. As the Court previously stated when Apotex tried to do the same, the legal analysis in the

⁹ Orchid’s reliance on *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379 (Fed. Cir. 1999) and *Seachange Int’l, Inc. v. C-Cor, Inc.*, 413 F.3d 1361 (Fed. Cir. 2005) is misplaced because these cases do not concern the entry of terminal disclaimers submitted in the context of a provisional obviousness-type double patenting rejection of copending applications prior to patent grant. Moreover, *Seachange* dealt with claim construction and not terminal disclaimer. And *Ex Parte Anthony*, 230 U.S.P.Q (BNA) 467 (Bd. App. 1982), the other case Orchid relies heavily upon, dealt with an issue of statutory interpretation as to whether a reissue patent may be granted under 35 U.S.C. § 251 for the sole purpose of withdrawing or cancelling a terminal disclaimer. *Id.* at 468. Thus, Orchid’s cases are inapposite.

¹⁰ As the later-issued patent, only the ‘157 patent could be disclaimed in order not to subject it to obviousness-type double patenting. *See, e.g., Bayer AG v. Barr Labs., Inc.*, 798 F. Supp. 196, 199 (S.D.N.Y. 1992) (“‘terminal disclaimer’ ... only disclaims that portion of a later-issued patent’s 17-year term that extends past the expiration date of an earlier-issued patent that makes claims that might subject the later-issued patent to obviousness-type double patenting.”); *see also Boehringer Ingelheim Int’l GmbH*, 592 F.3d at 1345 and *Eli Lilly & Co.*, 251 F.3d at 967.

Boeing case “is indeed correct” (Transcript of April 15, 2010 Court Hearing, Borchetta Decl., Exh. A at 43):

The Court, quite frankly, alternatively would conclude that the Court of Federal Claims decision in *Boeing Company vs. United States*, 69 Federal Claims 397, December of 2005, indeed is dispositive of the legal position of the defendant in this case.

The Court is satisfied that the *Boeing* decision appropriately relies upon Judge Rader’s decision in *Pharmacia Corporation vs. Parr*, 417 F.3d 1369, both of which essentially stand for the proposition that where a terminal disclaimer is filed, the fact that one of the patents ends up being terminated because of failure to pay the filing fees for an extension does not bring the terminal disclaimer into effect with regard to the other patent where the disclaimer has been filed in order to avoid obviousness type double patenting claims.

In short, the Court is satisfied that the legal analysis of the Court of Federal Claims is indeed correct... .

(*See id.* at 42-43.)

CONCLUSION

Orchid’s Rule 12(c) motion on its terminal disclaimer defense should be denied because there are disputed issues of fact and the motion does not present a purely legal issue. If the Court elects to address Orchid’s Rule 12(c) motion on the merits, it should be denied for the additional reason that a failure to pay maintenance fees on one patent does not bring a terminal disclaimer into effect for another patent where a disclaimer was filed to overcome an obviousness-type double patenting rejection.

Dated: February 7, 2011

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